

REMARKS

Recitations of claim 2 have been incorporated into claim 1. Accordingly, claim 2 has been cancelled. Claim 3 has been amended to recite that the heterologous nucleic acid comprises a recombination site. Claims 33-35 have been cancelled. No new matter has been added. Thus, entry of the amendments is respectfully requested. These amendments have been made pursuant to the agreement reached with the Examiner during the interview conducted on September 7, 2006. The Examiner's courtesies and suggestions with respect to prosecution have been greatly appreciated. Accordingly, this amendment is being presented to place claims 1 and 3-24 in condition for allowance.

Claims 1-24 and 33-35 have been rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement and written description. The Examiner has rejected the claims as lacking enablement on the basis that the excisable flanking sequences comprise transposable elements, without which recitation would render excision unpredictable. The Examiner has rejected the claims as lacking written description on the basis that the specification does not adequately describe the genus of sequences claimed, and therefore inadequately describes methods of using them and any resultant products. It is the Examiner's position that the specification only discloses cruciferous plant transformation with a single transposase sequence, and lacks guidance with regard to all other excisable sequences, transposons and recombinase sequences. Claims 2 and 33-35 have been cancelled making the rejections with respect to these claims moot. The cancellation of claims 33-35 also render the rejection under 35 U.S.C. § 102(b) moot. Applicants respectfully traverse the U.S.C. § 112 rejections as they apply to claims 1 and 3-24.

Applicants reiterate the agreement reached in the interview that amending claim 1 would suffice to overcome the

rejections based on U.S.C. § 112, first paragraph. Namely, independent claim 1 has been amended to further recite that the flanking sequences comprise transposable elements. In light of this amendment, Applicants submit that claims 1 and 3-24 are in full compliance with 35 U.S.C. § 112, first paragraph, meeting both the enablement and written description requirements. For the record however, the Examiner has cited the *Eli Lilly* case as support for requiring further description for the genus of sequences claimed herein. See *Univ. of CA v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997). However, in its most recent decision regarding the issue of written description as it applies to biotechnology cases, the Federal Circuit stated,

Eli Lilly does not set forth a per se rule that whenever a claim limitation is directed to a macromolecular sequence, the specification must always recite the gene or sequence, regardless of whether it is known in the prior art. . . Indeed, the forced recitation of known sequences in patent disclosures would only add unnecessary bulk to the specification.

*Falko-Funter Falkner v. Inglis*, 448 F.3d 1357 (Fed. Cir. 2006) (holding that the written description requirement does not require recitation of known genes or sequences). This case followed the Federal Circuit's prior ruling in *Capon v. Eshhar*, 418 F.3d 1349, 1356 (Fed Cir. 2005) (ruling that chimeric genes prepared from known DNA sequences of known function need not be analyzed and reported in the specification, and that there is no requirement to provide a re-description of what was already known.)

In this case, Applicants should not be required to disclose sequences of transposable elements or recombination

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sites suitable for use in the claimed methods. In any event, the present specification provides many examples of plants, transposons and recombinases/recombination site combinations and references several publications that demonstrate that such elements were known in the art. See, e.g., specification p. 10.

Thus, in light of the amendments and the foregoing discussion, Applicants submit that they were in possession of the subject matter set forth in claims 1 and 3-24 at the time the invention was made, and that one of skill in the art would be enabled to use the claimed methods based on the specification without undue experimentation. Applicants respectfully request reconsideration and withdrawal of the rejections.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

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Respectfully submitted,

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